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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,990	01/12/2001	Mingxu Xu	312762002600	1047

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EXAMINER	
NASHED, NASHAAT T	
ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/759,990	Applicant(s) Xu et al.
	Examiner Nashaat T. Nashed	Art Unit 1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 12, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above, claim(s) *9-21* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-8* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *6 & 13*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

The application has been amended as requested in the communication filed December 27, 2001.

Claims 1-21 are pending and under consideration.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I	Claims 1-8, drawn to a method assessing therapeutic levels of S-adenosylmethionine (SAM) in biological, classified in Class 435, subclass 15.
Group II	Claims 9-16, 20, and 21, drawn to a nucleic acid encoding S-adenosylhomocystiene hydrolase (SAHH) and a recombinant method to make SAHH, classified in Class 536, subclass 23.2, and classified in Class 435, subclass 195.
Group III	Claim 17, drawn to a method of measuring homocysteine in a biological sample, classified in Class 424, subclass 15.
Group IV	Claim 18, drawn to a composition comprising SAHH, classified in Class 435, subclass 195.
Group V	Claim 19, drawn to a method of depleting homocystine in biological fluids, classified in Class 424, subclass 94.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the method of Group I and the nucleic acid of Group II are not disclosed as capable of use together because the method of Groups I does not utilize the nucleic acid of Group II.

Inventions of Groups I, III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different invention are independent methods having different steps and produce different effects.

Inventions of Groups I and IV are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the composition of Group IV can be

used in a method of making antibodies against SAHH, whereas the method of Group I can be practiced with another SAHH.

Inventions of Groups II and those of Groups III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together because the method of Groups III and V do not utilize the nucleic acid of Group II.

The nucleic acid of Group II and the composition of His.SAHH of Group IV are independent chemical entities and require different searches in the patent and non-patent literature. Claims drawn to method of making protein composition using the recombinant DNA would be placed with the DNA of Group II because, although they have acquired a separate status in the art as shown by their different classification, they do not constitute a burden to search them in addition to the DNA sequences.

Inventions of Groups IV and V are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the composition of Group IV can be used in a method of making antibodies against SAHH, whereas the method of Group V can be practiced with another SAHH.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Kate H. Murashige on August 16, 2002 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-8.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and

(a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Specifically, Figures 6a-b contains nucleic acid sequences which are not part of the sequence listing and not identified by a sequence identification numbers. Also, through out the application, there are reference to the specific polypeptide HASS and His.HASS without identifying either with a sequence identification number or have the polypeptide sequences in the sequence listing. Page 15, example 7, contains nucleic acid sequence without being identified with a sequence identification number. Applicants are required to comply with the sequence rules by filing a new sequence listing in paper form and a computer readable form (CRF) containing all the missing sequences, and amend the specification by identifying the sequences by a sequence identification number including in the Figures or Figure description accompanied by a statement from the attorney of record indicating the new paper copy of the sequence listing and CRF do not contain new matter.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-6 are directed to a method of assessing the level of SAM in biological fluid which utilizes three independent enzymatic activities from any source. The enzymatic activities are glycine N-methyltransferase (GMT), S-adenosylhomocysteine hydrolase (SAHH), and homocysteinase (HCYase). Claims 7 and 8 are directed to a kit and a vague assay method, respectively, and using GMT and SAHH or His.SAHH. The specification, however, only provides a single representative species of SAHH and its derivative His. SAHH. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species. Also, the specification fails to describe additional

representative species of these SAHH by any identifying structural characteristics or properties other than the SAHH activity recited in claim 1, for which no predictability of structure is apparent. Also, the application fails to provide any teaching with regard to the source of both GMT and HCYase activities, i. e., commercial or biological source. In fact, there is no single example which demonstrate the claimed method is described. Given this lack of additional representative species and teaching as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Claims 1-8 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following are the reasons for the rejections:

(a) Claims 1, 7 and 8 contain the undefined abbreviations His.SAHH. There is no definition in the specification of His.SAHH, and one of ordinary skill in the art would not know its meaning. Abbreviations and acronyms must be defined at least once in the claims.

(b) Claim 8 is indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear to this examiner whether the claim is directed to "a method for determining the amount of SAM" or "an assay composition". Applicants must define clearly the metes and bound of the claimed invention. For examination purposes only, the claim is assumed to be directed to a method of determining SAM in a sample.

(c) Claims 2-6 are included with these rejections because they are dependent on rejected claim and do not cure its deficiencies.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is (703) 305-6586. The examiner can normally be reached Monday, Tuesday, Thursday, and Friday from 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone numbers for this Group are (703) 305-3014 and (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nashed

Nashaat T. Nashed, Ph. D.
Primary Examiner